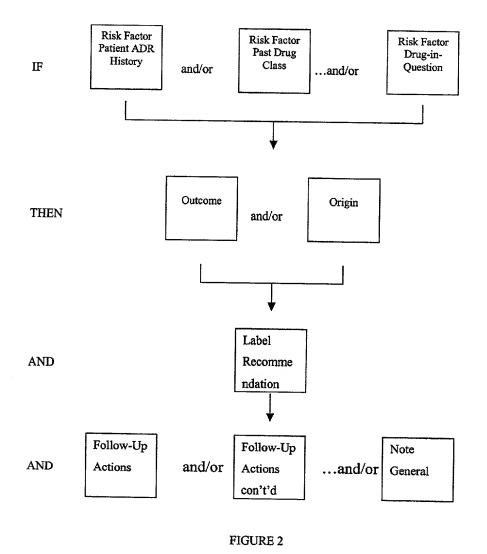


FIGURE 1



Category	Lexical Element	Lexical Element	Lexical Element
Risk factor (RF) patient history			
Risk due to past history			
RF patient ADR history	Sepsis	Hypersensitivity	Hypersensitivity
RF patient family history			
RF patient concurrent condition			
Risk due to current disease			
RF past drug		Enbrel	<enbrel component=""></enbrel>
RF past drug class			
RF concomitant drug			
RF concomitant drug class			
RF drug-in-question (DIQ) class	DMARD	DMARD	DMARD
RF DIQ	Enbrel (etanercept)	Enbrel (etanercept)	Enbrel (etanercept)
RF difference of gender			
RF age			
Outcome	Sepsis	Hypersensitivity	Hypersensitivity
Outcome origin			
Notes on outcome and resolution			
Prescribing action for DIQ	Contraindication	Contraindication	Contraindication
Follow-up actions			
Follow-up actions cont'd			
Conditional follow-up actions			
FUA condition			
FUA conditional action			
Instructions to patient		*	
Conditional instructions to patient			
ITP condition			
ITP conditional action			
What to remain alert for			
Not to be used as alternate therapy for			
Parameters to monitor			
What to test or check			
When to test or check			
Why/what to consider			
Prescribing notes to Physician			

FIGURE 3

Category	Lexical Element	Lexical Element
Risk factor (RF) patient history		<del>4</del>
Risk due to past history		
RF patient ADR history		
RF patient family history		
RF patient concurrent condition		
Risk due to current disease		
RF past drug		
RF past drug class		
RF concomitant drug		
RF concomitant drug class		
RF drug-in-question (DIQ) class	DMARD	DMARD
RF DIQ	Enbrel	Enbrel
RF difference of gender		
RF age		
Outcome	New infection	sepsis
Outcome origin		
Notes on outcome and resolution		1
Prescribing action for DIQ	Continue	Discontinue
Follow-up actions	Monitor closely	
Follow-up actions cont'd		
Conditional follow-up actions	Discontinue if new infection becomes serious	
FUA condition		
FUA conditional action		
Instructions to patient		
Conditional instructions to patient		
ITP condition		
ITP conditional action		
What to remain alert for		
Not to be used as alternate therapy for		
Parameters to monitor		
What to test or check		
When to test or check		
Why/what to consider		
Prescribing notes to Physician		

FIGURE 4

Figure 5: Sample of mapping a conditional text statement to a rule structure, using dictionary terms

## Label Text:

Celebrex should no	ot be given to patients who have demonstrated allergic-type reac	tions to sulfonomid
		1
Risk Category		
Risk Factor Patient past history		
Risk Factor Patient ADR history	Allergic-type reactions	
Risk factor Patient family history		
Risk Factor Patient concurrent condition		
Risk factor Past drug		i
Risk factor Past Drug Class	Sulfonomic	les
Risk Factor Concomitant Drug		
Risk Factor Concomitant drug class		
Risk Factor Drug-in-Question Class		
Risk factor Drug-in-Question Celebrex		
Outcome		
Outcome Origin		
Additional Notes on Outcome and Resolution		
Prescribing Action for Drug-in-Question Contra	aindicated	
Follow-up Actions		
Follow-up Actions cont'd		
Conditional Follow-up Actions		<del></del>
FUA Condition		
FUA Conditional action		
Instructions to Patient		
Conditional Instructions to Patient		
TTP Condition		
ITP Conditional action		
What to Remain Alert For		
Not to be used as Alternate Therapy For		
Parameters to Monitor		
What to Test/Check		
When to Test/Check		
Why/What to Consider		
Additional Prescribing Note to Physician		
Note General		

Figure 6: Sample of mapping a complex conditional text statement to a rule structure, using detionary terms Label Text:

Celebrex should not be given to patients with the aspirin triad. The symptom complex typically occurs in asthmatic patients who experience rhinitis with or without masal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAID's. Emergency help should be sought in cases where anaphylactoid reactions occur.

Nonio S. Emer	cite's neith should be strught in cases when	1 1			
Risk Category	1	! !	i i	Á	
Risk Factor Patient past history					
Risk Factor Patient ADR history	Rhinitis;	rhinitis with nasa	polyps; severe b	ronchospasm	
Risk factor Patient family history	1	1			
Risk Factor Patient concurrent condition	1				
Risk factor Past drug	Aspirin	triad	<u> </u>		
Risk factor Past Drug Class	NSAIDs	:	L		
Risk Factor Concomutant Drug			1	į .	
Risk Factor Concomitant drug class :				į .	
Risk Factor Drug-in-Question Class	: NSAIDs				
Risk factor Drug-in-Question Celebrex					
Outcome		<u> </u>			
Outcome Origin	:				
Addt'l Notes on Outcome and Resolution Potentially fatal b	ronchospasm				
Prescribing Action for Drug-in-Question	:		ļ		
Follow-up Actions			Infor	m patients	
Follow-up Actions cont'd					
Conditional Follow-up Actions	<u>j</u>				
FUA Condition	<u> </u>				
FUA Conditional action			<u> </u>		
Instructions to Patient	·				
Conditional Instructions to Patient	If anaphyla	ctoid reaction see	k emergency help		
	I				
ITP Condition Anaphylactoid	reaction		į.		
ITP Conditional action		Seek	emergency help		
What to Remain Alert For	1				
Not to be used as Alternate Therapy For					
Parameters to Monitor					
What to Test/Check					
When to Test/Check					
Why/What to Consider					
Additional Prescribing Note to Physician					
Note General					

Figure 7: Sample of reverse tracing mapping to original label

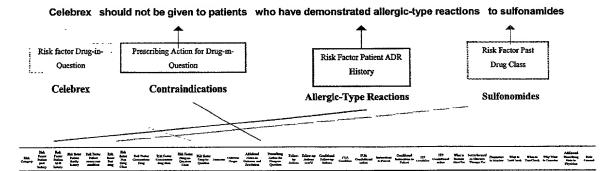
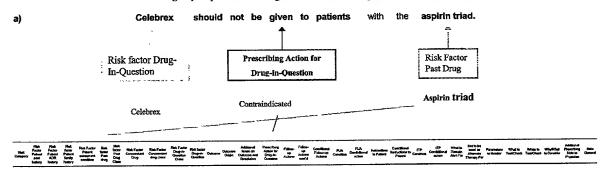
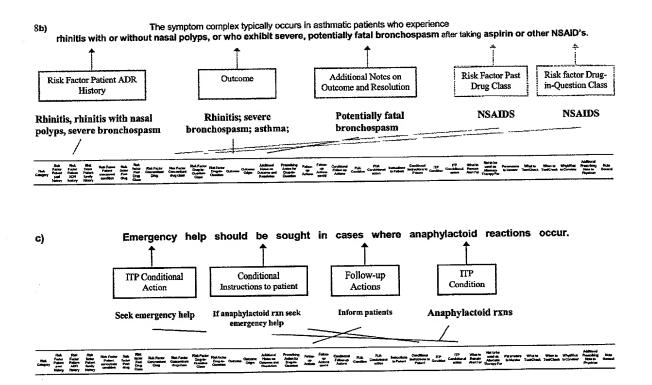


Figure 8: Sample of reverse tracing mapping to original label, in three parts

Label text: Celebrex should not be given to patients with the aspirin triad. The symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAID's. Emergency help should be sought in cases where anaphylactoid reactions occur.





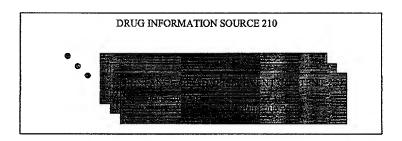


FIGURE 9

